Reviewer's report

Title: School based intervention to reduce anxiety in children: study protocol for a randomised controlled trial (PACES)

Version: 2 Date: 23 August 2012

Reviewer: Katharina Manassis

Reviewer's report:

I believe this protocol is suitable for publication in Trials and I do not believe I have any competing interests. My review is as follows:

1. Will the study design adequately test the hypothesis?

The authors hypothesize that the “FRIENDS” CBT program provided to 10-12 year old children at school by either school staff or health professionals will result in better outcomes for internalizing symptoms than “treatment as usual” (a general health curriculum). The primary outcome is symptoms on the Revised Child Anxiety and Depression Scale (RCADS), measured at baseline, 6 and 12 months to evaluate the program’s ability to both reduce such symptoms (secondary prevention) and prevent high levels of such symptoms (primary prevention).

I believe the study will adequately test this hypothesis. The design involves randomizing over 40 schools to the three possible treatment arms. Using the school as the unit of randomization (rather than the individual child) is a strength, as it avoids potential cross-contamination of conditions within a single school. The authors have also obtained ethical approval for a passive consent process (i.e. child participates unless parent objects) which will result in a high rate of participation. The likelihood of finding differences between the two active treatments and the comparison condition is high, given previous evidence related to FRIENDS and the authors’ careful attention to sample size.

Minor revision: It would be interesting to learn whether the authors anticipate any differences between the two active conditions. In other words: is FRIENDS optimally provided by school staff or by health professionals? Will the study answer this question? (please clarify)

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?

Overall, the authors have included most methodological details relevant to replication and comparison. There are a few areas that merit clarification, however.

Minor revisions:

a) In the description of the two main aims, the authors could clarify which aspects of the study relate primarily to which aim. For example, in the secondary
prevention (reduction of symptoms), I assume the first two time points will be used (baseline and 6 months), though this is not stated. I'm not sure what time points will be used for the primary prevention aim.

b) For the primary prevention, it is not clear how “high levels of anxiety and low mood” will be defined. Is there a particular t-score on the RCADS that will be used to define “high”? Since there is no diagnostic measure, this definition is particularly important for replication/comparison.

c) The content of the comparison condition (the Personal, Social, and Health Educational curriculum) is not clearly defined. Does that curriculum contain any mental health information or strategies that might overlap with FRIENDS (and thus reduce group differences)?

3. Is the planned statistical analysis appropriate?

The authors have paid careful attention to statistical issues. The use of an intent to treat analysis with adjustments for stratification variables and baseline scores is clearly appropriate. The methods used to minimize bias and address missing data are clearly described. My only concern is the possibility of ceiling effects. To clarify: when providing and evaluating a universal intervention (as in this trial), only a portion of the sample will have elevated symptoms to begin with. If the intervention succeeds, that portion of the sample will show decreased symptoms but the rest of the sample may have no room for improvement as their symptoms are already low or average. This can affect the overall chance of having statistically significant findings.

Discretionary revision: There may be a need to focus some analyses on those children who have high symptom levels to start, or at least to explain how any ceiling effects will be addressed.

4. Is the writing acceptable?

The writing is certainly acceptable and clear.

Discretionary revisions:

a) It would be helpful to include information at the end on the potential implications of the findings. For example, if the trial is successful, will the authors advocate for the broader use of one (if they can distinguish them) or both of the active treatment arms, and would that be economically feasible and sustainable in the long term?

b) The authors’ plans for dissemination of their findings to various audiences (mental health, educational, scientific) would also be of interest.

Minor issue not for publication:

Ethical approval and Consent (line 8): …required to provide signed assessment (I believe this word should be assent)

**Level of interest:** An article of outstanding merit and interest in its field
Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.